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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/659,622	09/11/2000	Henrik Sune Andersen	0776/1H462-US1	5060
23650	7590	10/20/2004	EXAMINER	
NOVO NORDISK PHARMACEUTICALS, INC			KRASS, FREDERICK F	
100 COLLEGE ROAD WEST				
PRINCETON, NJ 08540			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/659,622

**Applicant(s)**

ANDERSEN ET AL.

**Examiner**

Frederick F. Krass

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 28-36 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15, 19, 24 and 25 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28 and 32-36 is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-18, 20-23 and 29-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1614

### **Written Description Rejection**

The rejection of claims 1-13, 16-18, 20-23 and 29-31 under 35 U.S.C. 112, first paragraph for lack of written description is withdrawn in light of Applicant's arguments.

### **Scope of Enablement Rejection**

Claims 1-13, 16-18, 20-23 and 29-31 were rejected under 35 U.S.C. 112, first paragraph, for lack of enablement.

This rejection is maintained.

Applicant argues that, contrary to the examiner's assertion, the structural and spatial characteristics of suitable inhibitor compounds useful in the present invention are described at pages 50-62 and 77-79 of the present specification. Accordingly, one skilled in the art "could easily and readily determine what compounds fall within the scope of the claims and necessarily possess the features recited therein."

Various case law is cited to support Applicant's position. In particular, In re Angstadt is cited for the proposition that applicants "are not required to disclose every species encompassed by their claims even in an unpredictable art." Accordingly, Applicants argue, they "need not provide working examples for all embodiments of the invention. The examiner, moreover, has mis-characterized the level of guidance present in the instant specification, overstated the amount of experimentation required to determine specific PTPase inhibitors and underestimated the level of skill in the art."

The examiner does not agree. While Angstadt is indeed controlling law in this fact situation, the examiner believes the instant fact situation to be clearly distinguishable therefrom. The court stated at page 503 that:

Appellants have, in effect, provided those skilled in this art with a large but finite list of transition metal salts from which to choose in preparing such a

Art Unit: 1614

complex catalyst. Appellants have actually carried out 40 runs using various transition metal salts and hexalkylphosphoramides.

[...] One skilled in this art would merely have to substitute the correct mass of a transition metal salt for the transition metal salts disclosed in appellants' 40 runs.

[...] Since appellants have supplied the list of catalysts and have taught how to make and use them, we believe that the experimentation required to determine which catalysts will produce hydroperoxides would not be undue and certainly would not 'require ingenuity beyond that to be expected of one of ordinary skill in this art.'

This analysis applies exactly to instant claims 28 and 32-36, now allowed. It does not, however, apply to rejected claims 1-13, 16-18, 20-23 and 29-31. In the instant case, Applicants have not provided a "finite list" of potentially useful inhibitors. One would not "merely have to substitute" one potentially useful inhibitor compound for another – instead, he would have to synthesize particular compounds which are never actually disclosed, and which might not even exist. This is quite different from the situation in Angstadt, where the claims were drawn to specific compounds having complete structural formulae. Here, unspecified compounds having certain moieties, but no specific formula, are involved. Applicants have not supplied a list of inhibitors, nor have they taught how to make or use them, beyond those specifically recited by instant claim 28.

To practice the claimed invention according to the instant specification, one of ordinary skill in biotechnology/pharmacologic arts would additionally be required to be highly skilled in the art of organic synthesis. Even then, someone having that extraordinary level of skill would have to blindly experiment, attempting to synthesize theoretical compounds which might fall within the scope of the instant claims. This clearly requires "ingenuity beyond that to be expected of one of ordinary skill in this art"; and the examiner has not "mis-characterized the level of guidance present in the instant specification, overstated the amount of experimentation required to determine specific PTPase inhibitors and underestimated the level of skill in the art".

#### **Allowable Subject Matter**

Claims 28 and 32-36 are allowable as presently advised.

Art Unit: 1614

As discussed above, the allowed claims recite specific structural formulae, and thus encompass a "finite list" of inhibitors. In this context, further characterization by functionality (such as "interactions" with various enzyme sites) to select species within the general formula having optimized PTPase activity is acceptable and fully consistent with the reasoning provided in Angstadt.

#### **Action is Final**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;  
Tuesday: 10:30AM - 7PM;  
Wednesday: off;  
Thursday: 10:30AM- 7PM; and  
Friday: 10:30AM-7PM.

Art Unit: 1614

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

